



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC -2 1998

Ms. Kate Sutton
Regulatory Affairs Specialist
Osteonics Corporation
59 Route 17
Allendale, New Jersey 07401-1677

Re: K983870
Trade Name: Osteonics Restoration HA Hip Stem
Regulatory Class: II
Product Code: MEH
Dated: October 28, 1998
Received: November 2, 1998

Dear Ms. Sutton:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). This decision is based on consideration of the specific design of stem and coating composition detailed in this application. You may, therefore, market the device, subject to the general controls provisions of the Act and the following limitation:

You may not label or in any way promote these devices for "biological attachment, enhanced clinical or radiographic performance, enhanced fixation and/or long-term stable fixation." The data presented support equivalence with no additional claims over a conventional press-fit hip prosthesis (i.e., mechanical interlock, only).

Additional limitations for more specific claims of safety and effectiveness may be forthcoming. Should additional limitations be applied you will be contacted in writing to inform you of the additional labeling limitations.

The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

You may market your device under the above limitations as class II devices. These devices would be considered not substantially equivalent to a legally marketed predicate device if labeled with other intended uses and/or claims of safety or effectiveness. Any other intended uses or claims may cause the device to be classified into Class III under Section 513(f) of the Act. Class III devices are required to have an approved premarket approval (PMA) application prior to marketing.

Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

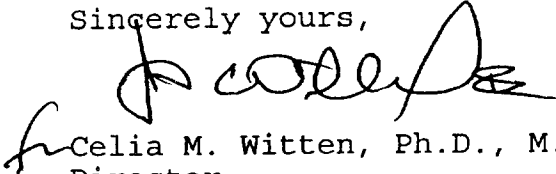
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be

Page 3 - Ms. Kate Sutton

obtained from the Division of Small Manufacturers Assistance
at its toll-free number (800) 638-2041 or (301) 443-6597 or at
its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K783870

Device Name: Osteonics® Restoration HA Stems

Indications For Use:

The indications for the use of the Osteonics® Restoration HA Stems , in keeping with those of other legally marketed Osteonics femoral components, are as follows:

For Use as a Bipolar Hip Replacement:

- Femoral head/neck fractures or non-unions.
- Aseptic necrosis of the femoral head.
- Osteo-, rheumatoid, and post-traumatic arthritis of the hip with minimal acetabular involvement or distortion.

Other Considerations:

- Pathological conditions or age considerations which indicate a more conservative acetabular procedure and an avoidance of the use of bone cement in the acetabulum.
- Salvage of failed total hip arthroplasty.

For Use as a Total Hip Replacement:

- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.

Additional Indication for Osteonics Head/Neck Stems:

- Clinical circumstances which require an altered femoral resection level due to a proximal fracture, bone loss or calcar lysis.

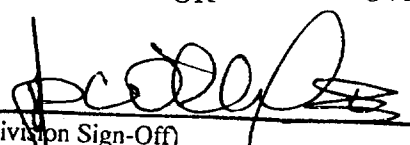
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____


(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K783870

(Optional Format 1-2-96)

DEC - 2 1998

K983870

**Special 510(k) - Device Modification
Summary of Safety and Effectiveness for the
Osteonics® Restoration HA Hip Stems**

Submission Information

**Name and Address of the Sponsor
of the 510(k) Submission:**

Osteonics Corporation
59 Route 17
Allendale, NJ 07401-1677

Contact Person:

Kate Sutton
Regulatory Affairs Specialist

Date of Summary Preparation:

October 28, 1998

Device Identification

Proprietary Name:

Osteonics® Restoration HA Hip Stems

Common Name:

Hip Prosthesis

Classification Name and Reference:

Hip Joint, Metal/Ceramic/Polymer, Semi-
Constrained, Cemented or Non-Porous
Uncemented Prosthesis
21 CFR §888.3353

Predicate Device Identification

The modified features of the Osteonics® Restoration HA Hip Stems are substantially equivalent to features of the following Osteonics predicate devices, which have been cleared for marketing via the 510(k) process:

- Osteonics® Restoration HA Hip Stems

Device Description

The Osteonics® Restoration HA Hip Stems are currently marketed devices that are being modified. The modification involves shortening the trunnion and reducing the diameter of the stem neck. Additionally, the neck length of each stem will be reduced by 5mm to better accommodate patient physiology. All other aspects of the Osteonics® Restoration HA Hip Stems will remain unchanged, with the exception of one feature on the longest stem (255mm). This stem currently features a distal tri-slot, which will be eliminated on the new version of the stem.

Intended Use:

The Osteonics® Restoration HA Hip Stems are single use components. They are intended for cementless fixation within the prepared femoral canals of patients requiring hip arthroplasty. The modified and predicate hip stems are intended to be used in conjunction with any commercially available Osteonics C-Taper femoral bearing head. For use as a total hip replacement, the modified and predicate stems may be used in conjunction with any legally marketed Osteonics acetabular component. The Osteonics® Restoration HA Hip Stems are manufactured from titanium alloy (ASTM F-620-96). The indications for the Osteonics® Restoration HA Hip Stems include the following:

For Use as a Bipolar Hip Replacement:

- Femoral head/neck fractures or non-unions.
- Aseptic necrosis of the femoral head.
- Osteo-, rheumatoid, and post-traumatic arthritis of the hip with minimal acetabular involvement or distortion.

Other Considerations:

- Pathological conditions or age considerations which indicate a more conservative acetabular procedure and an avoidance of the use of bone cement in the acetabulum.
- Salvage of failed total hip arthroplasty.

For Use as a Total Hip Replacement:

- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.

Additional Indication for Osteonics Head/Neck Stems:

- Clinical circumstances which require an altered femoral resection level due to a proximal fracture, bone loss, or calcar lysis.

Performance Data:

Mechanical testing has been performed to demonstrate the substantial equivalence of this Osteonics stem design to predicate stem designs in terms of its fatigue strength.

Statement of Technological Comparison:

All features of the Osteonics® Restoration HA Hip Stems will remain the same with the following exceptions: 1) The distal tri-slot on the longest stem will be eliminated, 2) the neck diameter on each stem will be slightly reduced and the neck length will be reduced by 5mm, and 3) the trunnion will be shortened slightly.